Notice of Allowability	Application No.	Applicant(s)	
	08/501,743	FAHIM ET AL.	
	Examiner	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *9-10-04 and 2-18-05*.

2. ☒ The allowed claim(s) is/are *29, 30, 35, 31-33, 36, 38 and 42; now renumbered 1-9 respectively*.

3. ☐ The drawings filed on _____ are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☒ to Paper No./Mail Date *#7; 6/13/97*.
   (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892) 4 sheets
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date attached
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Michael Stewart, 24973 on February 10, 2005 and February 18, 2005.

2. A decision by the Board of Patents Appeals and Interferences was rendered on September 10, 2004 regarding Appeal No. 2001-2180 Application No. 08/501743. The rejections under 102 and 103 over Englund for claims 27, 28, 31-34, 38, 39 and 42 were affirmed. The rejections under Englund for claims 36 and 37 were affirmed. The rejections under 102 and 103 over Englund for claims 29 and 30 were reversed. The rejection under Englund for claim 35 was reversed.

Claims 27, 28, 34, 37 and 39 have been canceled. Claims 29, 30 and 35 have been deemed allowable in view of the Board Decision of September 10, 2004 and the amendment to the claims set forth below. Claims 31-33, 36, 38 and 42 have been amended to depend from allowed claim 35. Claims 29, 30-33, 35, 36, 38 and 42 have been allowed in this application.

3. The application has been amended as follows:

Specification, p. 1, l. 8-10

This application is a continuation-in-part of copending United States patent application no. 08/433,646 filed May 4, 1995, now U. S. Patent 5,877,298.

1-26. Canceled

27-28. Canceled

29. (Amended) A vaccine composition for protecting an at-risk human population against a case of a disease (whooping cough) caused by infection of *B. pertussis*, which comprises [The vaccine of claim 28 containing] about 10 μg nitrogen of pertussis toxoid, about 5 μg nitrogen of filamentous haemagglutinin, about 5 μg nitrogen of pertactin and about 3 μg nitrogen of agglutinogens of *B pertussis*, all in pure form, in a single human dose, in amounts to confer protection to the extent of at least about 70% of members of the at-risk population.

30. (Amended) A vaccine composition for protecting an at-risk human population against a case of a disease (whooping cough) caused by infection of *B. pertussis*, which comprises [The vaccine of claim 28 containing] about 20 μg nitrogen of pertussis toxoid, about 20 μg nitrogen of filamentous haemagglutinin, about 5 μg nitrogen of pertactin and about 3 μg nitrogen of agglutinogens of *B pertussis*, all in pure form, in a single human dose, in amounts to confer protection to the extent of at least about 70% of members of the at-risk population.

31. (Amended) The vaccine of claim [27] 35 wherein the extent of protection is at least about 80% for a case of pertussis having a spasmodic cough of duration at least 21 days and confirmed bacterial infection.

32. (Amended) The vaccine of claim [27] 35 wherein the extent of protection is at least about 70% for a case of mild pertussis having a cough of at least one day duration.

33. (Amended) The vaccine of claim [28] 35 wherein the extent of protection is about 85% for a case having a spasmodic cough of duration at least 21 days and confirmed bacterial infection.

34. Canceled

35. (Amended) A vaccine composition for protecting an at-risk human population against a case of a disease (whooping cough) caused by infection of *B. pertussis*, which comprises [The vaccine of claim 34] pertussis toxoid, filamentous haemagglutinin, pertactin and agglutinogens of *B pertussis*, all in pure form, in amounts to confer protection to the extent of at least about 70% of members of the at-risk population; wherein said agglutinogens comprise fimbrial agglutinogen 2 (Agg 2) and fimbrial agglutinogen 3 (Agg 3) substantially free from agglutinogen 1; wherein the weight ratio of Agg 2 to Agg 3 is from about 1.5:1 to about 2:1.

36. (Amended) The vaccine of claim [27] 35 further comprising tetanus toxoid and diphtheria toxoid.

37. Canceled

38. (Amended) The vaccine of claim [27] 35 further comprising an adjuvant.

39. Canceled

42. (Amended) A method of immunizing an at-risk human population against disease caused by infection by *B. pertussis*, which comprises administering to members of the at-risk human population an immunoeffective amount of the vaccine composition of claim [27] 35 to confer protection to the extent of at least about 70% of the members of the population.

3. Claims 29, 30, 35, 31-33, 36, 38 and 42 are allowed and have been renumbered 1-9 respectively.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5. It is noted that the formal drawings are now required and that Applicant should comply with the objections to the drawings as set forth in Form 948 (Draftsperson's Notice) mailed with Paper No. 7 filed June 13, 1997. Applicant should make sure that the figure descriptions set forth in the specification match the formal drawings that will be submitted.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 571-272-0860. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
February 21, 2005

CLEAN COPY OF CLAIMS

1
~~29~~. A vaccine composition for protecting an at-risk human population against a case of a disease (whooping cough) caused by infection of *B. pertussis*, which comprises about 10 μg nitrogen of pertussis toxoid, about 5 μg nitrogen of filamentous haemagglutinin, about 5 μg nitrogen of pertactin and about 3 μg nitrogen of agglutinogens of *B pertussis*, all in pure form, in a single human dose, in amounts to confer protection to the extent of at least about 70% of members of the at-risk population.

2
~~30~~. A vaccine composition for protecting an at-risk human population against a case of a disease (whooping cough) caused by infection of *B. pertussis*, which comprises about 20 μg nitrogen of pertussis toxoid, about 20 μg nitrogen of filamentous haemagglutinin, about 5 μg nitrogen of pertactin and about 3 μg nitrogen of agglutinogens of *B pertussis*, all in pure form, in a single human dose, in amounts to confer protection to the extent of at least about 70% of members of the at-risk population.

3
~~35~~. A vaccine composition for protecting an at-risk human population against a case of a disease (whooping cough) caused by infection of *B. pertussis*, which comprises pertussis toxoid, filamentous haemagglutinin, pertactin and agglutinogens of *B pertussis*, all in pure form, in amounts to confer protection to the extent of at least about 70% of members of the at-risk population; wherein said agglutinogens comprise fimbrial agglutinogen 2 (Agg 2) and fimbrial agglutinogen

3 (Agg 3) substantially free from agglutinogen 1; wherein the weight ratio of Agg 2 to Agg 3 is from about 1.5:1 to about 2:1.

4 3
~~31.~~ The vaccine of claim ~~35~~ wherein the extent of protection is at least about 80% for a case of pertussis having a spasmodic cough of duration at least 21 days and confirmed bacterial infection.

5 3
~~32.~~ The vaccine of claim ~~35~~ wherein the extent of protection is at least about 70% for a case of mild pertussis having a cough of at least one day duration.

6 3
~~33.~~ The vaccine of claim ~~35~~ wherein the extent of protection is about 85% for a case having a spasmodic cough of duration at least 21 days and confirmed bacterial infection.

7 3
~~36.~~ The vaccine of claim ~~35~~ further comprising tetanus toxoid and diphtheria toxoid.

8 3
~~38.~~ The vaccine of claim ~~35~~ further comprising an adjuvant.

9
~~42.~~ A method of immunizing an at-risk human population against disease caused by infection by *B. pertussis*, which comprises administering to members of the at-risk human population an immunoeffective amount of the vaccine composition of claim 3 ~~35~~ to confer protection to the extent of at least about 70% of the members of the population.